

REMARKS

Prior to examination of this application on the merits, Applicants respectfully request entry of the foregoing preliminary amendment. Applicants respectfully assert that the amendment introduces no prohibited new matter.

Applicants respectfully submit that no prohibited new matter has been introduced by the foregoing amendments. Claims 92-129 are pending before the Examiner for examination. Claims 55-91 have been canceled. Support for the new claims can be found throughout the specification and in the original claims. Specifically, support for claims 92 and 111 can be found on page 40, line 29, through page 42, line 14 (method of predicting a toxic effect of a test compound or hepatotoxicity by comparing one or more gene expression levels in a toxin-exposed sample to a database comprising quantitative gene expression information from liver samples exposed to the test compound and to the excipient in which that compound is prepared). The Examiner is also directed to allowed U.S. Application Serial No. 10/152,319 with similar claim structure.

The Office Action dated December 1, 2004 has been carefully reviewed and the following response is made in response thereto. In view of the following remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

I. Summary of the Office Action

1. The Office Action rejected claims 55-89, under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.
2. The Office Action rejected claims 55-89, under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as their invention.
3. The Office Action rejected claims 55-58, 62-70, 72-79, 81 and 84-88 under 35 U.S.C. §103(a) as being unpatentable over Friend et al. (US 6,218,122) taken with Cunningham et al. (US 6,372,431).

II. Response to the Office Action

Rejection of claims 55-89 under 35 U.S.C. §112, first paragraph

The Office Action alleges that claims 55-89 contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time of the application was filed, had no possession of the claimed invention. Specifically, the Examiner alleges that the limitation “quantitative gene expression.. of the test compound” in claims 55, 86, and 88 has no support in the specification. Furthermore, the recitation “the mean expression level for that gene in the toxin-exposed cell or tissue samples” in claim 62 and the recitation of the limitation “control liver cell or tissue samples that have been exposed to the excipient” in claim 77 also allegedly lack support in the specification. In response, claims 55, 62, 77, 86, and 88, and their dependent claims have been canceled, rendering the rejection moot. The currently pending claims no longer recite these limitations although Applicants submit that such limitations are expressly found in the instant specification, such as in Tables 3A-3S that disclose the Group Mean (toxin exposed) and Non Group Mean (excipient exposed) values.. Accordingly, Applicants respectfully request the rejections be withdrawn.

Rejection of claims 55-89 under 35 U.S.C. §112, second paragraph

The Office Action alleges that claims 55, 86 and 88, along with their dependent claims 56-85, 87 and 89, are indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Purportedly, claims 55, 86 and 88 have been regarded as vague and indefinite because the steps of the claims comprise preparing and comparing gene expression profiles while the preamble recites a method of predicting a toxic effect or a method of predicting hepatotoxicity. The Examiner questions whether the comparison in step (b) is meant to compare expression profile to the whole database or to a specific data set contained within the database. Claims 55-89 have been canceled. To address the Examiner’s concern, Claim 92 and its dependent claims recite that the gene expression profiles are compared to the genes expression profiles in Tables 3A-3S. Support for the amendment can be found in original claims 78-80. In light of the amendment, Applicants respectfully submit that step (b) of claim 92 is clear and definite with respect to the specific data set to be compared. In view of the amendment, Applicants respectfully

request that the rejections under 35 U.S.C. §112, second paragraph, be withdrawn.

Rejection of claims 55-58, 62-70, 72-79, 81, and 84-88 under 35 U.S.C. §103(a)

The Office Action alleges that claims 55-58, 62-70, 72-79, 81 and 84-88 are unpatentable over Friend *et al.* (U.S. Patent No. 6,218,122 B1) taken with Cunningham *et al.* (U.S. Patent No. 6,372,431 B1). Claims 55-58, 62-70, 72-79, 81 and 84-88 have been canceled, rendering the rejection moot. Applicants respectfully submit that the pending claims which recite particular gene profiles in Tables 3A-3S are not obvious in view of this combination of references, wherein neither reference discloses the genes of Tables 3A-3S or a database comprising gene expression levels for those genes in toxin exposed liver cell or liver tissue samples.

Conclusion

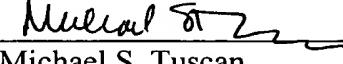
In view of the foregoing remarks, the Applicants respectfully request withdrawal of all outstanding rejections and early notice of allowance to that effect. Should the Examiner find that an interview would be helpful to further prosecution of this application, he is invited to telephone the undersigned at his convenience.

Except for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,
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